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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,501	08/25/2003	Carl T. Allenspach	01139/3/US	2375

26648 7590 04/16/2007
PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,501	ALLENSPACH ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *24-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 are pending in the application. Claims 24-29 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-23 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-23 remain/are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Nadkarni et al. (US 2002/0013357 Pub. Date: 01/31/2002).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Nadkarni et al. disclose pharmaceutical compositions containing from about 1 mg to about 100 mg of valdecoxib useful in treatment of cyclooxygenase-2-mediated conditions and

disorders (Abstract). Nadkarni et al. disclose that the tablet compositions contain pregelatinized starch (National Starch 1500: a corn starch) in the same amount, 20 mg, as the instant application (Page 8, Tables 1 and 2 and claims 1, 4, 6 and 7). Applicant teaches the same pregelatinized starch in the tablet (instant specification, page 21 Table 1). It is the Examiner's position that since the same pregelatinized starches are taught in the same amount then the tablet disclosed by Nadkarni et al. would have low viscosity and/or exhibit a multimodal particle size distribution and read on instant claims 1-6, 17 and 19. Nadkarni et al. disclose valdecoxib particles have a D_{90} less than about 75 μm (Claim 9) and can be present from about 4 mg to about 40 mg per dose and reads on instant claims 7 and 8 (Claim 4). Nadkarni et al. disclose a tablet wherein the excipients comprise one or more diluents in an amount of about 5% to about 99%, one or more disintegrants in an amount of about 0.2% to about 30%, one or more binding agents, starch, is present in an amount of about 0.5% to about 25%, and one or more lubricants in an amount of about 0.1% to about 10%, by weight of the composition thus anticipating instant claims 20-22 (Claim 5). Nadkarni et al. disclose a tablet wherein the excipients comprise lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, pregelatinized starch and magnesium stearate thus anticipated instant claim 23 (Claim 7).

Instant claims 9-17 are directed to shear stress values for the pregelatinized starch. Since the disclosure of Nadkarni et al. teaches the exact same pregelatinized starch in the exact same amount as the instant application, then it is the Examiner's position, without evidence to the contrary, that the pregelatinized starch of the disclosure of Nadkarni et al. inherently has those properties. Please note that the Office is not equipped with the proper equipment to test the myriad number of ways an Applicant might measure a variable. When the prior art appears to

disclose the same exact components in the same amounts then the burden is shifted to Applicant to demonstrate the difference.

Response to arguments:

Applicant asserts that the alleged inherent properties of "National Starch 1500" are not supported by the data appearing in the application and that it cannot be assumed that all types of pregelatinized starch would have low viscosity because it does not appear to be common feature. The Examiner cannot agree. Applicant has only argued and not shown any data with "National Starch 1500". Claim 1 is drawn to pregelatinized starch and, in the absence of evidence to the contrary, the cited art of record reads on the invention and would inherently have low viscosity and multimodal particle size distribution.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-23 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Nadkarni et al. (WO 01/41761 A2).

Nadkarni et al. disclose pharmaceutical compositions containing from about 1 mg to about 100 mg of valdecoxib useful in treatment of cyclooxygenase-2-mediated conditions and disorders (Abstract). Nadkarni et al. disclose that the tablet compositions contain pregelatinized starch (National Starch 1500: a corn starch) in the same amount, 20 mg, as the instant application

(Page 21, Table 1 and claims 1, 4, 6 and 7). Applicant teaches the same pregelatinized starch in the tablet (instant specification, page 21 Table 1). It is the Examiner's position that since the same pregelatinized starches are taught in the same amount then the tablet disclosed by Nadkarni et al. would have low viscosity and/or exhibit a multimodal particle size distribution and read on instant claims 1-6, 17 and 19. Nadkarni et al. disclose valdecoxib particles have a D_{90} less than about 75 μm (Claim 9) and can be present from about 4 mg to about 40 mg per dose and reads on instant claims 7 and 8 (Claim 4). Nadkarni et al. disclose a tablet wherein the excipients comprise one or more diluents in an amount of about 5% to about 99%, one or more disintegrants in an amount of about 0.2% to about 30%, one or more binding agents, starch, is present in an amount of about 0.5% to about 25%, and one or more lubricants in an amount of about 0.1% to about 10%, by weight of the composition thus anticipating instant claims 20-22 (Claim 5). Nadkarni et al. disclose a tablet wherein the excipients comprise lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, pregelatinized starch and magnesium stearate thus anticipated instant claim 23 (Claim 7).

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Response to arguments:

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Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

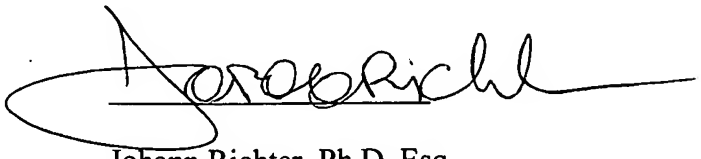
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616



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